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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/854,248 | 05/11/2001 | Michael Salgaller | 020093-000810US | 7931 |
| 20350 | 7590 | 07/06/2004 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | | EWOLDT, GERALD R |
| | | ART UNIT | | PAPER NUMBER |
| | | 1644 | | |

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/854,248 | SALGALLER ET AL. |
| | Examiner | Art Unit |
| | G. R. Ewoldt, Ph.D. | 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 29 March 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 10 and 12-21 is/are pending in the application.
 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 10, 12-14, 16-21 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

1. Claims 10, 12-14 and 16-21 are being acted upon.
2. Applicant's amendments and remarks, filed 3/29/04 are acknowledged. In view of Applicant's amendments, the previous objection to the claims and the rejection under the first paragraph of 35 U.S.C. 112 have been withdrawn.
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. Claims 10, 12-14 and 16-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,788,963 (1998, IDS) in view of Ramoner et al. (1998, IDS) for the reasons of record as set forth in the action mailed 9/25/03.

Applicant's arguments, filed 3/29/04, have been fully considered but they are not persuasive. Applicant argues that "the Examiner has not taken into consideration all of the elements of the claims nor has any reasons for suggesting a reasonable basis for an expectation of success been provided. Claim 10 recites "exposed *in vitro* to an antigen and bacillus Calmette Guerin (BCG) or BCG with lipopolysaccharide (LPS) to promote Major Histocompatibility Complex- (MHC-) class I processing of the antigen." In the remarks of the Examiner stating the basis for this rejection there is no discussion of the limitation that the exposure of the DCs to the antigen and BCG or BCG and LPS result in a MHC-class I response. In fact, Ramoner et al. do not disclose or suggest the use of BCG, or BCG with LPS, combined with an antigen can promote an MHC-class I response."

Applicant's argument regarding the instant inventor's reasons for administering antigen- and BCG-exposed DCs to a patient comprise only further characterization of a method made obvious by the prior art. Further characterization of a method does not render a method patentably distinct. In the instant situation, the secondary reference (Ramoner et al.) provides adequate motivation for exposing antigen loaded DCs to BCG for use in tumor therapy (i.e., administration to a patient in need

thereof). As set forth in the reference, BCG had been used to treat tumors, BCG was known to stimulate DCs, and the authors even suggested the use of BCG with DCs in tumor immunotherapy. Note that the reasons for combining the methods of the prior art need not be the same reasons as those of the instant inventors. The fact that the instant inventors theorize that BCG promotes an anti-tumor response through the promotion of MHC class I processing of antigens is irrelevant to patentability because said processing would have occurred in the method of the combined references. Accordingly, adequate motivation to combine the references has been established and the rejection has been maintained.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

8. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Serial No. 09/854,248
Art Unit 1644

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Additionally, the Technology Center receptionist can be reached
at (571) 272-1600.

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Primary Examiner
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GR Ewoldt
6/28/01
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PRIMARY EXAMINER